DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 95N–0139]

Medical Devices; Proposed Reclassification and Exemption From Premarket Notification for Certain Classified Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of July 28, 1995 (60 FR 38902). The document proposed to reclassify 112 generic types of class II devices into class I based on new information respecting the devices, and exempt the 112 generic types of devices, along with 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. The document was published with some errors. This document corrects those errors.

DATES: Submit written comments by October 11, 1995. For the devices the agency is proposing to reclassify into class I and exempt from the requirement of premarket notification, FDA is proposing that any final rule that may issue based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

In FR Doc. 95–18456, appearing on page 38902 in the **Federal Register** of Friday, July 28, 1995, the following corrections are made:

1. On page 38902, in the third column, under the **DATES** caption, in the second sentence, ''August 28, 1995'' is corrected to read ''30 days after the date of its publication in the **Federal Register**.''

2. On page 38906, in the first column, in Table 4.—ANESTHESIOLOGY DEVICES, ''868.1975 Water Vapor Analyzer'' is added after ''868.1870 Gas volume calibrator''.

Dated: August 28, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–21737 Filed 8–31–95; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AD-FRL–5290–3]

Clean Air Act Proposed Approval of the Federal Operating Permits Program; San Luis Obispo Air Pollution Control District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing interim approval for the Federal Operating Permits Program submitted by the California Air Resources Board on behalf of the San Luis Obispo County Air Pollution Control District (San Luis Obispo or District). This Program was submitted for the purpose of complying with Federal requirements in title V of the Clean Air Act which mandates that States develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

DATES: Comments on this proposed action must be received in writing by October 2, 1995.

ADDRESS: Comments should be addressed to Frances Wicher, Mail Code A–5–2, U.S. Environmental Protection Agency, Region IX, Air and Toxics Division, 75 Hawthorne Street, San Francisco, California 94105.

Copies of the District's submission and other supporting information used in developing the proposed interim approval including the Technical Support Document are available for inspection during normal business hours at the following location: Operating Permits Section, A–5–2, Air and Toxics Division, U.S. EPA-Region IX, 75 Hawthorne Street, San Francisco, California 94105.

FOR FURTHER INFORMATION CONTACT: Frances Wicher, (415) 744–1250, Operating Permits Section, A–5–2, Air and Toxics Division, U.S. EPA-Region IX, 75 Hawthorne Street, San Francisco, California 94105.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

As required under title V of the Clean Air Act (''the Act'') as amended (1990), EPA has promulgated rules that define the minimum elements of an approvable State operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of State operating permits programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 CFR part 70. Title V requires States to develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

The Act requires that States develop and submit these programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within one year of receiving the submission. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, EPA may grant the program interim approval for a period of up to two years. If EPA has not fully approved a program by two years after the November 15, 1993 date, or by the end of an interim program, it must establish and implement a Federal program.

II. Proposed Action and Implications

A. Analysis of State Submission

The analysis contained in this notice focuses on the major elements of San Luis Obispo's title V operating permit program and on the specific elements that must be corrected to meet the minimum requirements of part 70. The full program submittal, the Technical Support Document (TSD), which contains a detailed analysis of the submittal, and other relevant materials are available for inspection as part of the public docket. The docket may be viewed during regular business hours at the address listed above.

1. Title V Program Support Materials

San Luis Obispo's title V program was submitted by the California Air Resources Board (CARB) on November 15, 1993. Additional material was submitted by CARB on May 23 and August 21, 1995 and by the District on February 18, 1994 and May 3, 1995. In submitting the District's title V program, CARB requested source category-limited interim approval for the program because California law currently exempts agricultural sources from all permitting requirements including title V. The District's submission contains a complete program description, District implementing and supporting regulations, application and reporting

forms, and other supporting information. In addition, CARB submitted for all Districts in the State a single Attorney General's opinion, State enabling legislation, and certain other information regarding State law.

EPA reviewed the District's program to assure that it contains all the elements required by § 70.4(b) (elements of the initial program submission) and has found the program complete pursuant to § 70.4(e)(1) in a letter to the CARB on January 13, 1994. An implementation agreement is currently being developed between San Luis Obispo and EPA.

2. Title V Operating Permit Regulations and Program Implementation

The rules that San Luis Obispo adopted to implement its title V program are Rules 216 *Federal Part 70 Permits* (adopted October 26, 1993) and Rules 217 *Federal Part 72 Permits* (adopted March 29, 1995). Other District rules that were submitted in support of the District's title V program are Rules 103 *Conflicts between District, State and Federal Rules* (no date), 105 *Definitions* (revised October 26, 1993), 107 *Breakdown or Upset Conditions and Emergency Variances* (revised March 29, 1995), 201 *Equipment Not Requiring a Permit* (revised November 5, 1991), 206 *Conditional Approval* (revised November 5, 1991) and 301–308 *Fees* (various adoption and revision dates).[1] These rules, along with the authorities granted the District under California State law, substantially meet the requirements of §§ 70.2 (Definitions) and 70.3 (Applicability) for applicability; § 70.5(c) (Standard application form and required information) for criteria that define insignificant activities and for complete application forms; §§ 70.4(b)(12) (Section 502(b)(10) changes) and 70.6 (Permit content) for permit content including operational flexibility; § 70.7 (Permit issuance, renewal, reopenings, and revisions) for public participation, permit issuance, and permit modifications; § 70.9 (Fee determination and certification) for fees; and § 70.11 for enforcement authority.

EPA has identified several interim approval issues affecting permit content, permit modifications and notice to the public and affected states that must be corrected in order for the San Luis Obispo program to receive full approval. These interim approval issues are discussed below and detailed in the TSD. EPA has also identified in the TSD other recommended changes that are not required for full approval but would improve, clarify, or strengthen the District's title V program.

a. Variances

The San Luis Obispo District Hearing Board has authority to issue variances from requirements imposed by State and local law. See California Health and Safety Code 42350 *et seq.* and District Rule 107 and Regulation VII. In the opinion submitted with California operating permit programs, California's Attorney General states that ''(t)he variance process is *not* part of the Title V permitting process and does not affect federal enforcement for violations of the requirements set forth in a Title V permit.'' (Emphasis in original.)

EPA regards State and District variance provisions as wholly external to the programs submitted for approval under part 70 and consequently is proposing to take no action on these provisions of State and local law. EPA has no authority to approve provisions of state law that are inconsistent with the Act. EPA does not recognize the ability of a District to grant relief from the duty to comply with a federally-enforceable part 70 permit, except where such relief is granted through procedures allowed by part 70. A part 70 permit may be issued or revised, consistent with part 70 permitting procedures, to incorporate those terms of a variance that are consistent with applicable requirements. A part 70 permit may also incorporate, via part 70 permit issuance or revision procedures, the schedule of compliance set forth in a variance. However, EPA reserves the right to pursue enforcement of applicable requirements notwithstanding the existence of a compliance schedule in a permit to operate. This is consistent with § 70.5(c)(8)(iii)(C), which states that a schedule of compliance ''shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based.''

b. Permit Content

San Luis Obispo's permit content requirements are found in sections F. and L. of Rule 216 and in the District's Part 70 Permit Format. The Part 70 Permit Format is San Luis Obispo's sample permit form and was submitted as part of the District's title V program. The regulatory provisions adequately address nearly all of the part 70 requirements; however, certain elements (e.g., §§ 70.6(a)(3)(ii)(A) and 70.6(a)(6)(i)), are addressed or more fully detailed only in the Part 70 Permit Format. Nothing in the District's program requires the use of the Part 70 Permit Format for every permit issued pursuant to Rule 216. EPA is, therefore, requiring, as a condition for full approval, that San Luis Obispo establish a binding requirement that the Part 70 Permit Format be included in all part 70 permits or that the District fully address all part 70 permit content requirements in Rule 216.

EPA is specifically approving the Part 70 Permit Format (dated November 13, 1993) contained in Appendix B–6 of the District November 15, 1993 submittal. Any modifications to the conditions established in this Format must be approved by EPA. Failure to include these conditions in part 70 permits will be cause for EPA to object to a District operating permit. See § 70.8(c)(1).

c. Insignificant Activities

Section 70.4(b)(2) requires States to include in their title V programs any criteria used to determine insignificant activities or emission levels for the purpose of determining complete applications. Section 70.5(c) states that an application for a part 70 permit may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate appropriate fee amounts. Section 70.5(c) also states that EPA may approve, as part of a State program, a list of insignificant activities and emissions levels which need not be included in permit applications. Under part 70, a State must request and EPA must approve as part of that State's program any activity or emission level that the State wishes to consider insignificant. Part 70, however, does not establish appropriate emission levels for insignificant activities, relying instead on a case-by-case determination of appropriate levels based on the particular circumstances of the part 70 program under review.

San Luis Obispo submitted, as an insignificant activities list, its permit exemption rule (Rule 201) which specifies a specific list of activities and, for unlisted activities, an emissions cap of 2 lb/day (0.365 tons per year) that will be considered insignificant in the District's title V program. Rule 201, however, does not allow any activities that are subject to a New Source Performance Standard or National Emission Standard for Hazardous Air Pollutants to be considered insignificant. In addition, the District submitted an emissions analysis of its list of insignificant activities.

[1] EPA is only approving those portions of Rules 105, 107, 206 and 301–308 that are necessary to implement the District's title V program. More specifically, EPA is not approving the emergency variance provisions of Rule 107 B. This approval does not constitute approval under any other provisions of the Act.

San Luis Obispo County is designated attainment for all criteria pollutants; therefore, the major source threshold for all non-HAPs regulated air pollutants is 100 tons per year and, for HAPs, 10 tons per year for a single HAP and 25 tpy for a combination of HAPs. The District's emissions cap for insignificant activities is less than ½ of 1 percent of the major source threshold for all non-HAPs regulated air pollutants and less than 5 percent of the major source threshold for HAPs. EPA finds these levels to be insignificant and the 2 lb/day cap to be fully approvable.

EPA, however, in reviewing the District list of specific activities did find several activities that are potentially subject to a unit-specific applicable requirement. Rule 201 M.1. and 2. exempts air conditioning and refrigeration units regardless of size. Such units, if they have a charge rate of 50 pounds or more of a Class I or II ozone-depleting compounds, would be subject to applicable requirements and could not be considered insignificant.

The TSD provides a detailed review of the District's insignificant activities list. For interim approval, EPA is relying on San Luis Obispo's Rule 216 which requires the inclusion in each permit application of a list of all activities that are insignificant based on size or production rate and all information necessary to determine the applicability of, and to impose applicable requirements. For full program approval San Luis Obispo must revise its list of insignificant activities for title V permitting as discussed in section B.2. of this notice.

d. Definition of Title I Modification

The San Luis Obispo program does not explicitly define the term ''title I modification,'' however, the program effectively defines the term to mean ''the modification does not involve any addition, deletion, or revision to a part 70 permit condition under section 112(g) of Title I of the CAA, or under EPA regulations promulgated pursuant to Title I of the CAA, including 40 CFR parts 51, 52, 60, 61, and 62.'' See, for example, Rule 216 C.13., definition of ''Minor Part 70 Permit Modification.'' While this effective definition is broad enough to cover minor new source review (minor NSR) changes because it includes changes under parts 51 and 52, it is clear from the Program Description that the District does not intend that minor NSR be considered a title I modification.

In an August 29, 1994 rulemaking proposal, EPA explained its view that the better reading of ''title I modifications'' includes minor NSR. However, the Agency solicited public comment on whether the phrase should be interpreted to mean literally any change at a source that would trigger permitting authority review under regulations approved or promulgated under title I of the Act. (59 FR 44572, 44573). This would include State preconstruction review programs approved by EPA as part of the State Implementation Plan under section 110(a)(2)(C) of the Clean Air Act.

The EPA has not yet taken final action on the August 29, 1994 proposal. However, in response to public comment on that proposal, the Agency has decided that the definition of ''title I modifications'' is best interpreted as not including changes reviewed under minor NSR programs. This decision was announced in a June 20, 1995 letter from Mary D. Nichols, EPA Assistant Administrator for Air and Radiation, to Congressman John D. Dingell, and will be included in a supplemental rulemaking proposal that will be published in August, 1995. Thus, EPA expects to confirm that San Luis Obispo's definition of ''title I modification'' is fully consistent with part 70.

The August 29, 1994 action proposed to, among other things, allow State programs with a more narrow definition of ''title I modifications'' to receive interim approval (59 FR 44572). The Agency stated that if, after considering the public comments, it continued to believe that the phrase ''title I modifications'' should be interpreted as including minor NSR changes, it would revise the interim approval criteria as needed to allow states with a narrower definition to be eligible for interim approval. If EPA does conclude, during this rulemaking, that Title I modifications should be read to include minor NSR, it will implement the interim approval option spelled out in the August 29, 1994 proposal.

e. Affected State Notification

The San Luis Obispo program neither defines ''affected state'' nor includes any procedures for notifying and dealing with comments from affected states as required by § 70.2 ''Affected state'', § 70.8(b) and § 70.7(e)(2)(ii). In its program submittal, the District argued that it need not include these procedures because its location (on the coastline in the middle of California) precludes emissions from its sources from affecting any other states. EPA would agree with this position if the definition of ''affected state'' was not being revised to include tribal governments that request treatment as affected states. Because there are tribal lands that could qualify as affected states for San Luis Obispo, the District may in the future need to have affected state notification and response procedures in its title V program.

EPA has not finalized the rulemaking that will allow tribal governments to seek affected state status. EPA is proposing, as an interim approval issue for the District, that Rule 216 be revised to define and provide for giving notice to and responding to comments from affected states. Since it remains uncertain whether any tribes will seek affected state status for the San Luis Obispo District, EPA is proposing as an alternative that the District may satisfy the interim approval issue by making a commitment to: (1) Initiate rule revisions upon being notified by EPA of an application by a tribe for state status, and (2) provide affected state notice to tribes upon their filing for state status (i.e., prior to San Luis Obispo's revising Rule 216 to incorporate affected state notice procedures).

3. Permit Fee Demonstration

Section 502(b)(3) of the Act requires that each permitting authority collect fees sufficient to cover all reasonable direct and indirect costs required to develop and administer its title V operating permits program. Each title V program submission must contain either a detailed demonstration of fee adequacy or a demonstration that aggregate fees collected from title V sources meet or exceed $25 per ton of emissions per year (adjusted from 1989 by the Consumer Price Index (CPI)). The $25 per ton amount is presumed, for program approval, to be sufficient to cover all reasonable program costs and is thus referred to as the ''presumptive minimum,'' (§ 70.9(b)(2)(i)).

San Luis Obispo has opted to make a presumptive minimum fee demonstration in order to show fee adequacy and meet the requirements of § 70.9 (Fee determination and certification). San Luis Obispo's existing fee schedule (Rules 301–308) requires title V facilities to pay an amount equivalent to $61 per ton in annual operating fees (1991 figures). This amount is well over the $25 per ton per year (CPI adjusted from 1989) presumptive minimum.

San Luis Obispo determined its fee level at the $61 per ton equivalent amount by assessing its 1991 fee revenue and costs, and the additional costs posed by title V. San Luis Obispo is prepared to increase fees, as needed, to reflect actual program implementation costs.

4. Provisions Implementing the Requirements of Other Titles of the Act

a. Authority and Commitments for Section 112 Implementation

San Luis Obispo has demonstrated in its title V program submission adequate legal authority to implement and enforce all section 112 requirements through the title V permit. This legal authority is contained in the State of California enabling legislation and in regulatory provisions defining ''federally enforceable requirements'' and stating that the permit must incorporate all applicable requirements. EPA has determined that this legal authority is sufficient to allow San Luis Obispo to issue permits that assure compliance with all section 112 requirements. For further discussion on the District's legal authority, please refer to the TSD accompanying this rulemaking and the April 13, 1993 guidance memorandum titled ''Title V Program Approval Criteria for Section 112 Activities,'' signed by John Seitz, Director, Office of Air Quality Planning and Standards, U.S. EPA.

b. Authority for Title IV (Acid Rain) Implementation

On May 23, 1995, CARB submitted on behalf of San Luis Obispo, the District's rule Rule 217 *Federal Part 72 Permits* (adopted March 29, 1995). Rule 217 incorporates by reference 40 CFR part 72 *(Acid Rain) Permit Regulation* and provides the District adequate authority to issue permits to affected acid rain sources under title IV.

B. Proposed Action

1. Title V Operating Permits Program

The EPA is proposing to grant interim approval to the operating permits program submitted by CARB on behalf of the San Luis Obispo County Air Pollution Control District on November 15, 1993, and supplemented on February 18, 1994, and May 3, May 23 and August 21, 1995. If EPA were to finalize this proposed interim approval, it would extend for two years following the effective date of final interim approval, and could not be renewed. During the interim approval period, San Luis Obispo would be protected from sanctions, and EPA would not be obligated to promulgate, administer and enforce a federal permits program for the District. Permits issued under a program with interim approval have full standing with respect to part 70, and the one-year time period for submittal of permit applications by subject sources begins upon the effective date of interim approval, as does the three-year time period for processing the initial permit applications.

Following final interim approval, if the District failed to submit a complete corrective program for full approval by the date six months before expiration of the interim approval, EPA would start an 18-month clock for mandatory sanctions. If San Luis Obispo then failed to submit a corrective program that EPA found complete before the expiration of that 18-month period, EPA would be required to apply one of the sanctions in section 179(b) of the Act, which would remain in effect until EPA determined that the District had corrected the deficiency by submitting a complete corrective program. Moreover, if the Administrator found a lack of good faith on the part of the District, both sanctions under section 179(b) would apply after the expiration of the 18-month period until the Administrator determined that the District had come into compliance. In any case, if, six months after application of the first sanction, the District still had not submitted a corrective program that EPA found complete, a second sanction would be required.

If, following final interim approval, EPA were to disapprove San Luis Obispo's complete corrective program, EPA would be required to apply one of the section 179(b) sanctions on the date 18 months after the effective date of the disapproval, unless prior to that date the District had submitted a revised program and EPA had determined that it corrected the deficiencies that prompted the disapproval. Moreover, if the Administrator found a lack of good faith on the part of the District, both sanctions under section 179(b) would apply after the expiration of the 18-month period until the Administrator determined that the District had come into compliance. In all cases, if, six months after EPA applied the first sanction, San Luis Obispo had not submitted a revised program that EPA had determined corrected the deficiencies that prompted disapproval, a second sanction would be required.

In addition, discretionary sanctions may be applied where warranted any time after the end of an interim approval period if a district has not timely submitted a complete corrective program or EPA has disapproved a submitted corrective program. Moreover, if EPA has not granted full approval to a District title V operating permits program by the expiration of an interim approval and that expiration occurs after November 15, 1995, EPA must promulgate, administer and enforce a federal permits program for that district upon interim approval expiration.

2. Interim Approval Issues for San Luis Obispo's Title V Operating Permits Program

If EPA finalizes this interim approval, San Luis Obispo must make the following changes, or changes that have the same effect, to receive full approval:

(1) Remove any activities from the District's list of insignificant activities that are subject to a unit-specific applicable requirement. See §§ 70.4(b)(2) and 70.5(c).

(2) Revise the definitions of ''Minor Part 70 Permit Modification'' in Rule 216 C.13, to ensure that significant changes to existing monitoring permit terms or conditions, rather than just relaxations of existing monitoring terms, are processed as significant permit modifications. See § 70.7(e)(4).

(3) Revise Rule 216 J.1.b. to include notice ''by other means if necessary to assure adequate notice to the affected public.'' See § 70.7(h)(1).

(4) Revise Rule 216 H.1.a.4. and L.1.e. to further limit the types of significant permit modifications that may be operated prior to receiving a final part 70 permit revision to only those modifications that are subject to section 112(g) or required to have a permit under title I, parts C and D of the Act and that are not otherwise prohibited by an existing part 70 permit. See § 70.5(a)(1)(ii).

(5) Revise Rule 216 to establish a binding requirement that the Part 70 Permit Format will be included in all part 70 permits or revise Rule 216 to fully address all part 70 permit content requirements within the Rule. See § 70.6.

(6) Revise Rule 216 to define and provide for giving notice to and responding to comments from affected states. Alternatively, San Luis Obispo may make a commitment to: (1) Initiate rule revisions upon being notified by EPA of an application by a tribe for state status, and (2) provide affected state notice to tribes upon their filing for state status (i.e., prior to revising Rule 216 to incorporate affected state notice procedures). See §§ 70.2 ''Affected state,'' 70.7(e)(2)(iii), and 70.8(b).

(7) Limit the exemption in Rule 216 D.4 for solid waste incineration units required to obtain a permit pursuant to section 3005 of the Solid Waste Disposal Act to those units that are not a major source. Section 70.3(b) states that all major sources, affected sources (acid rain sources), and solid waste incinerators regulated pursuant to section 129(e) of the CAA may not be exempted from title V permitting.

Although section 129(g)(1) of the CAA exempts solid waste incineration units subject to section 3005 of the Solid Waste Disposal Act from regulation under section 129, these units are still subject to title V and part 70 if they are also major sources. See § 70.3(a)(1).

(8) Revise Rule 216 H.4. to require that the permittee keep records describing non-federal minor changes (e.g., off-permit changes) and the emissions resulting from these changes. See § 70.4(b)(14)(iv).

3. California Enabling Legislation—Legislative Source Category Limited Interim Approval Issue

Because California State law currently exempts agricultural production sources from permit requirements, CARB has requested source category-limited interim approval for all California districts. EPA is proposing to grant source category-limited interim approval to the operating permits program submitted by CARB on behalf of San Luis Obispo on November 15, 1993. In order for this program to receive full approval (and to avoid a disapproval upon the expiration of this interim approval), the Health and Safety Code must be revised to eliminate the exemption of agricultural production sources from the requirement to obtain a title V permit. Once the California statute has revised, the District must also revise its permit exemption rules to eliminate any blanket exemption granted agricultural sources.

The above described program and legislative deficiencies must be corrected before San Luis Obispo can receive full program approval. For additional information, please refer to the TSD, which contains a detailed analysis of San Luis Obispo's operating permits program and California's enabling legislation.

4. District Preconstruction Permit Program Implementing Section 112(g)

The EPA has published an interpretive notice in the **Federal Register** regarding section 112(g) of the Act (60 FR 8333, February 14, 1995). The revised interpretation postpones the effective date of section 112(g) until after EPA has promulgated a rule addressing that provision. The interpretive notice explains that EPA is considering whether the effective date of section 112(g) should be delayed beyond the date of promulgation of the federal rule so as to allow States time to adopt rules implementing the federal rule, and that EPA will provide for any such additional delay in the final section 112(g) rulemaking. Unless and until EPA provides for such an additional postponement of section 112(g), San Luis Obispo must be able to implement section 112(g) during the period between promulgation of the federal section 112(g) rule and adoption of implementing District regulations.

For this reason, EPA is proposing to approve the use of San Luis Obispo's preconstruction review program as a mechanism to implement section 112(g) during the transition period between promulgation of the section 112(g) rule and adoption by San Luis Obispo of rules specifically designed to implement section 112(g). However, since the sole purpose of this approval is to confirm that the District has a mechanism to implement section 112(g) during the transition period, the approval itself will be without effect if EPA decides in the final section 112(g) rule that there will be no transition period. The EPA is limiting the duration of this proposed approval to 12 months following promulgation by EPA of the section 112(g) rule.

5. Program for Delegation of Section 112 Standards as Promulgated

Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by EPA as they apply to part 70 sources. Section 112(l)(5) requires that the state program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under part 70. Therefore, EPA is also proposing to grant approval under section 112(l)(5) and 40 CFR part 63.91 of San Luis Obispo's program for receiving delegation of section 112 standards that are unchanged from federal standards as promulgated. California Health and Safety Code section 39658 provides for automatic adoption by CARB of section 112 standards upon promulgation by EPA. Section 39666 of the Health and Safety Code requires that districts then implement and enforce these standards. Thus, when section 112 standards are automatically adopted pursuant to section 39658, San Luis Obispo will have the authority necessary to accept delegation of these standards without further regulatory action by the District. The details of this mechanism and the means for finalizing delegation of standards will be set forth in a Memorandum of Agreement between San Luis Obispo and EPA, expected to be completed prior to approval of the District's section 112(l) program for delegation of unchanged federal standards. This program applies to both existing and future standards but is limited to sources covered by the part 70 program.

III. Administrative Requirements

A. Request for Public Comments

The EPA is requesting comments on all aspects of this proposed interim approval. Copies of the District's submittal and other information relied upon for the proposed interim approval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed interim approval. The principal purposes of the docket are:

(1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the approval process, and

(2) To serve as the record in case of judicial review. The EPA will consider any comments received by October 2, 1995.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permits programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed approval action promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the

aggregate, or to the private sector. This federal action approves pre-existing requirements under State or local law, and imposes no new federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 21, 1995.

Felicia Marcus,

Regional Administrator.

[FR Doc. 95–21761 Filed 8–31–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 649, 650, and 651

[Docket No. 950824215–5217–02; I.D. 050295B]

RIN 0648–AH37

American Lobster Fishery, Framework Adjustment 1; Atlantic Sea Scallop Fishery, Framework Adjustment 3; Northeast Multispecies Fishery, Framework Adjustment 7; Vessel Ownership Requirements

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes measures contained in Framework Adjustment 1 to the American Lobster Fishery Management Plan (FMP), Framework Adjustment 3 to the Atlantic Sea Scallop FMP, and Framework Adjustment 7 to the Northeast Multispecies FMP. These framework adjustments would revise a provision in each of the FMPs that requires all permit applicants to own a fishing vessel at the time they apply for or renew a Federal limited access permit. This proposed action would allow certain applicants who have owned vessels that meet the various limited access permit qualification criteria, but who do not currently own a vessel, to preserve their eligibility to apply for a limited access permit for a replacement vessel in subsequent years by obtaining a Confirmation of Permit History.

DATES: Comments on the proposed rule must be received on or before September 15, 1995.

ADDRESSES: Comments on the proposed rule or supporting documents should be sent to Dr. Andrew A. Rosenberg, Regional Director, Northeast Region, NMFS, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Proposed Framework Adjustments to Vessel Ownership Requirements.''

Copies of the Framework Adjustments, Amendment 5 to the American Lobster FMP, Amendment 4 to the Atlantic Sea Scallop FMP, and Amendment 5 to the Northeast Multispecies FMP, including regulatory impact reviews, initial regulatory flexibility analyses, and final supplemental environmental impact statements are available upon request from Douglas Marshall, Executive Director, New England Fishery Management Council, 5 Broadway, Saugus, MA 01906–1097; telephone: 617–231–0422.

FOR FURTHER INFORMATION CONTACT: E. Martin Jaffe, Fishery Policy Analyst, 508–281–9272.

SUPPLEMENTARY INFORMATION:

Background

In 1994, NMFS implemented major amendments developed by the New England Fishery Management Council (Council) to the FMPs for the Atlantic sea scallop, northeast multispecies and the American lobster fisheries. These amendments, which were intended to address overfishing in these fisheries, implemented measures that limited access to these fisheries based upon historical participation.

NMFS partially implemented Amendment 4 to the Atlantic Sea Scallop FMP (January 19, 1994, 59 FR 2757) and Amendment 5 to the Northeast Multispecies FMP on March 1, 1994 (59 FR 9872). Most of the measures remaining became effective on May 1, 1994 (59 FR 22760, May 3, 1995). NMFS implemented the approved sections of Amendment 5 to the American Lobster FMP on June 21, 1994 (59 FR 31938).

Under current regulations for the Atlantic sea scallop and northeast multispecies fisheries, to be eligible to obtain a Federal limited access permit in 1994, an applicant had to have owned a vessel that qualified under the limited access criteria for each respective fishery. In addition, an applicant had to obtain a permit in 1994 to be eligible to renew a limited access permit in future years. Current regulations for the American lobster fishery are the same, with the exception that the qualifying year is 1995. These requirements represent a continuation of preexisting permit requirements.

Under a limited access permit system, however, this situation poses a potential problem for anyone who does not own a fishing vessel at the time he or she applies for, or renews, a limited access permit. This includes anyone who sold or transferred a vessel and retained the permit and fishing history, but did not buy a new vessel in time to apply for an initial Atlantic sea scallop or northeast multispecies permit during the 1994 calendar year, or, in the case of American lobster, during the 1995 calendar year.

In developing Amendment 5 to the American Lobster FMP, Amendment 4 to the Atlantic Sea Scallop FMP, and Amendment 5 to the Northeast Multispecies FMP, the Council adopted the policy that vessel owners should not be required to continue to fish their vessels to be eligible to obtain or renew limited access permits. The Council did not intend to force vessels to remain active in currently overfished fisheries to retain fishing rights for the future, but it did not explicitly address the issue of vessel ownership as a requirement to obtain a permit under the various FMP amendments. Therefore, current regulations contradict the Council's intent not to require vessels to remain active in a limited access fishery.

Proposed Adjustment

To address this problem, the Council has requested NMFS to implement this proposed action, which would allow an applicant who has owned a vessel that meets the various limited access permit qualification criteria, but who does not own a vessel at the time of application, to preserve his or her right to qualify for a Federal limited access permit for a replacement vessel in subsequent years in the Atlantic sea scallop and northeast multispecies fisheries, and in the American lobster fishery. Qualified applicants would be allowed to apply for a Confirmation of Permit History, and would need to apply for such annually, to preserve the permit and fishing history of the qualifying vessel.

Comments and Responses

The Council has discussed and heard public comment on this issue for several years during the development of the amendments to the Northeast Multispecies and Atlantic Sea Scallop FMPs. More recently, this problem was discussed at the September 21–22, 1994, Council meeting, at which time the